December 17, 2001

MEMORANDUM TO: Claudia M. Craig, Section Chief
Facilities Decommissioning Section
Decommissioning Branch, DWM

FROM: John T. Buckley **/RA/**
Facilities Decommissioning Section
Decommissioning Branch, DWM

SUBJECT: MEETING REPORT FOR THE DECEMBER 10 - 13, 2001, MEETING WITH MALLINCKRODT INC.

From December 10 - 13, 2001, U.S. Nuclear Regulatory Commission (NRC) staff members met with representatives of Mallinckrodt Inc. (Mallinckrodt) to discuss NRC comments associated with its Phase 1 Decommissioning Plan (DP). In addition, Decommissioning Branch management discussed Mallinckrodt's schedule for submittal of the Phase 2 DP. Attached is the meeting report documenting this meeting.

Attachment: Meeting Report

Docket: 040-06563
License: STB-401

MEETING REPORT

Date: December 10 - 13, 2001

Time: 8:00 am to 4:00 pm

Place: U.S. Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852

Purpose: To Discuss NRC's Comments on Mallinckrodt Inc.'s Phase 1 Decommissioning Plan

Attendees:	NRC	Mallinckrodt
	John Buckley	Mark Puett
	Jean-Claude Dehmel	Jim Adams
	Claudia Craig	Mark Burkot
	Larry Camper	Henry Morton
	Dominick Orlando	Jim Grant

Background:

On November 11, 1997, Mallinckrodt Inc. (Mallinckrodt) submitted its Phase 1 Decommissioning Plan (DP) to the U.S. Nuclear Regulatory Commission (NRC) for review and approval. Phase 1 of the decommissioning process includes demolition or decontamination of above ground buildings and equipment. Phase 2 includes the cleanup of surface and subsurface soils and building foundations. Mallinckrodt is scheduled to submit its Phase 2 DP in December 2001. Most (approximately 80%) of the contamination at the Mallinckrodt facility is being remediated under the U.S. Department of Energy's Formerly Utilized Sites Remedial Action Program (FUSRAP) program managed by the Army Corps of Engineers. The NRC portion of the facility is being cleaned up by Mallinckrodt to terminate its NRC license.

Discussion:

On February 12, 1999, NRC completed its review of the Mallinckrodt Phase 1 DP and provided Mallinckrodt a request for additional information (RAI). Mallinckrodt responded to the RAI by submitting a revised Phase 1 DP, to NRC, on March 24, 2000. NRC's review of the revised DP resulted in a second RAI, which was transmitted to Mallinckrodt on August 7, 2000. An NRC inspection at Mallinckrodt on October 13, 2000, resulted in additional RAIs dated October 20, 2000, and December 13, 2000. Mallinckrodt resubmitted their DP on January 29, 2001. An additional meeting resulted in RAI questions and responses in July 2001 between Mallinckrodt and the NRC. In November 2001, NRC sent one last RAI. This meeting was the result of both parties agreeing to the final wording to meet all requests for additional information from the NRC.

The major objectives of this four day meeting was to resolve all outstanding technical issues raised in NRC's RAIs, and come to an agreement on the text revisions necessary to make the Phase 1 DP acceptable to the NRC. On December 10, 2001, Mallinckrodt and NRC staff discussed the major technical issues and generally agreed on a resolution approach for each

Attachment

issue. On December 11 - 12, 2001, meeting participants discussed each section of the DP, and generated the text necessary to resolve all NRC comments.

The last item on the agenda was a discussion about Mallinckrodt's schedule for submittal of the Phase 2 DP. On October 22, 2001, Mallinckrodt requested to delay submittal of the Phase 2 DP, by 18 months, to June 2003. Decommissioning Branch (DCB) management is concerned that lengthy delays erode public confidence in the decommissioning process. Therefore, DCB management wanted to discuss the technical and programmatic issues affecting Mallinckrodt's Phase 2 DP schedule. Mallinckrodt provided the attached summary of issues, for purposes of discussion. One of the major concerns raised by Mallinckrodt during the discussion, was the turnover in NRC staff since the beginning of the project. It was noted that, to date, there have been six health physics reviewers and three project managers assigned to the Mallinckrodt project. Mallinckrodt believes that these personnel changes have resulted in multiple reviews, causing unnecessary delays in approving the Phase 1 DP. In response to this concern, Larry Camper committed to Mallinckrodt, that NRC would not change Project Managers or Health Physics reviewers for the remainder of the Mallinckrodt project, barring unforseen circumstances such as promotion or termination of employment.

The meeting was adjourned at 10:45 am.

Actions:

1. Mallinckrodt will revise the Phase 1 DP and resubmit to NRC for final review.

2. Mallinckrodt will provide the previously requested financial assurance information to NRC no later than January 4, 2002.

3. NRC will deny Mallinckrodt's request to delay submittal of the Phase 2 DP by 18 months. Instead, NRC will approve a 12 month delay, which results in a scheduled transmittal date of January 2003.

CONCERNS

1. **MALLINCKRODT WANTS TO DECOMMISSION**
    1. C-T is in the middle of major narcotics operations needed for future site development.
    2. Mallinckrodt wants use of the land area for future growth and to rid itself of the deteriorating, unsightly CT process buildings.
    3. Mallinckrodt is concerned that the 40.13(a) exemption that enables it to dispose of waste material in RCRA cells at WCS Texas will be rescinded. We are aware of the State of Colorado petition and NRC staff activity on this issue.
    4. Mallinckrodt has reserved sufficient funds for decommissioning and has been ready to start and finish decommissioning for more than 4 years.
    5. Mallinckrodt had an extensive characterization survey done to support decommissioning.

    This 4 year delay has been discouraging to us about the NRC regulatory process.

2. MALLINCKRODT HAS BEEN SUPPORTIVE OF THE DECOMMISSIONING RULEMAKING AND THE MARSSIM

Mallinckrodt was a constructive participant in the decommissioning rulemaking and in development of the MARSSIM.

Decommissioning Rulemaking

1. Attended most of the decommissioning workshops.
2. HM & TP submitted an analysis of the ALARA methodology used in the draft GEIS supporting the decommissioning rulemaking and provided an alternative methodology. In the final draft GEIS, the NRC replaced its method with the one we proposed.
3. Derived a more efficient ALARA equation for use in Regulatory Guide DG-4006. It is now in SRP Appendix D.
4. Presented “Issues and Problems in Measuring Alpha-Emitting Radionuclides on Surfaces” to an NRC decommissioning workshop.
5. Presented “Interpretation of the Relation of Building Interior Surface to Airborne Radioactivity,” to an NRC decommissioning workshop.
6. Examined surface dust to airborne transfer studies related to resuspension.
7. Performed a study, “Estimating Whether the Maximum Residual Radionuclide Concentration Allowed in Soil Can Be Distinguished from Background.”
8. Perfected a beta radiation measurement technique for final status surveys on surfaces.
9. Made a presentation of decommissioning issues to be resolved to the Fuel Cycle Facilities Forum.
10. Prepared comments on the decommissioning rulemaking and contributed them to the Fuel Cycle Facilities Forum for submission to the NRC.

Attachment

MARSSIM

1. During development of the MARSSIM, Mallinckrodt designed, performed, and evaluated some characterization surveys as close to MARSSIM conventions as knowledge enabled us to do. We shared prominent things we learned with MARSSIM committee members.
2. Informally shared a best effort MARSSIM survey design procedure with MARSSIM committee members.
3. A presentation to the MARSSIM committee describing methods to interpret background from characterization survey data when an independent background is not available. That resulted in conceptual acceptance in Regulatory Guide DG-4006.
4. A presentation to the EPA Science Advisory Board, Radiation Advisory Committee describing problems recognized during characterization surveys. As a result,
   - a new NUREG-1505 chapter 12 was written to deal with the multiple materials & multiple backgrounds in a survey unit problem; and
   - a new NUREG-1505, section 13.2 was written to deal with the multiple background problem.
5. Informed NRC staff that a MARSSIM, Appendix I, Table 1 application was reversed and advised of other errors.
6. Attended the field comparison of EML *in-situ* gamma spectrometry versus ORISE soil sampling and laboratory analysis.

3. ANTICIPATED NRC CONCERNS

3.1 Why has Mallinckrodt not submitted Phase 2 of its decommissioning plan?

Reasons:

- We have always planned the decommissioning plan and decommissioning in two phases: first buildings, then land.
- Mallinckrodt discussed this two-phase process with the NRC early in the project. It was acceptable to the NRC staff.
- We have put our effort mainly on Phase 1 first.
- After responding to each request for additional information, we expected to get Phase 1 approval. Then we could concentrate plan preparation on the 2nd phase. For instance, we expected approval about July 2000 on the basis of a letter from L. Camper. In a meeting involving Rich Clement, we expected no more RAI.
- We have not been able to get Phase 1 approved.
- Since the submittal in January 2001, believing that Phase 1 would be approves soon, we have worked to get implementation procedures ready.
- We were led to believe that approval of Phase I plan would help MI prepare and submit Phase II. This discussion first occurred during meeting to discuss applicability of Standard Review Plan in February, 2001.
- The USACE and NRC met without Mallinckrodt, and then had further discussions with Mallinckrodt about the delineation issues.

3.2 What caused delay in submitting Phase 2 of the decommissioning plan?

Reasons:

- Mallinckrodt and the NRC Staff have focused our attention and effort mainly on Phase 1.
- Multiple health physics reviews of Phase I D Plan questions (Eric Abelquist of ORISE, Richard Clement, Jean-Claude Dehmel, and Boby Eid of EPAB) produced additional RAI and required response and revision.
- NRC has not approved a release criteria for Phase I which also impacts how we submit Phase II for streets and pavement.
- We have been uncertain about what USACE interjection during mid-2001 would have, for instance on delineation of FUSRAP versus Mallinckrodt responsibilities, including unreacted ore burial areas.
- Why have 2 applications under review when we cannot get one approved?

3.3 Why does Mallinckrodt need and deserve more time?

Reasons:

- The extensions to date have been consumed mainly by characterization survey, Phase 1 D Plan preparation, and NRC review of the Phase 1 decommissioning plan.
- It will take time to complete Phase 2.
- The NRC staff recommended looking into using FUSRAP ROD criteria. Mallinckrodt needs additional evaluation of the alternatives. (The FUSRAP ROD criteria differ from NRC decommissioning criteria and USACE interpretation of NRC criteria, dose assessment, and the MARSSIM differ somewhat.)
- NRC has not approved surface release criterion and has asked us to hold the release criteria on a mass or volume basis in abeyance, which may affect how to release pavement and streets.
- The USACE has not seemed to want to resolve FUSRAP delineation to date. As a result, the URO burial area delineation remains an issue with the USACE. (The USACE has taken differing attitude than the DOE concerning the FUSRAP.)
- During our last major meeting, July 27, 2001, between Mallinckrodt and NRC, we discussed that December was not possible because of issues about and work on Phase 1. We were asked to submit a letter at least a couple of months in advance.

3.4 Why have there been so may NRC requests for information? Does that reflect inadequate preparation?

Reasons:

- NRC requests for information may reflect several things:

1. Multiple NRC reviewers, including 4 group leaders, 3 project managers, and 6 health physicists.
2. The NRC standard review plan (SRP) evolved after Mallinckrodt submitted Phase 1 of the plan. Some RAI stems from the SRP, *e.g.*, requests for of final status survey design specifics beyond the final status survey plan in the DP.
3. NRC evolution of implementation policy, *e.g.*, the 2 RAI in the NRC letter of November 15.
4. The RAI and discussions have sought more detailed description than we expected.

! We do not believe the number of items in RAI reflect inadequate preparation.

4. MALLINCKRODT CONCERNS

4.1 Consider what Mallinckrodt has to do in perspective.

! Remove 2 process and 1 support buildings to regulated burial.
! Perform final status surveys on process labs and non-process buildings nearby.
! The source is natural uranium series and thorium series

4.2 Long Time

About 49 months have elapsed since Mallinckrodt submitted Phase 1 of its DP.

From request to response, it has taken NRC 31 months and Mallinckrodt 18 months. Considering overlap, it has been completely in NRC hands 27 months and in Mallinckrodt hands 6 month

4.3 Multiple Reviewers and a Succession of Reviews

Since beginning characterization survey planning, multiple NRC staff:

! 6 health physicists
David Fauver
Donna Moser Smith
Eric Abelquist
Richard Clement
Jean-Claude Dehmel
EPAB

! 3 project managers
Charles Gaskin
Richard Turtil
John Buckley

! 4 group leaders
NMSS
Larry Bell
Robert Nelson
Claudia Craig

- 3 branch chiefs
  - Robert Pierson
  - John Hickey or Mike Weber
  - Larry Camper

HM has explained the survey method to 5 successive health physicists and apparently inquiry from the EPAB.

We believed most issues were resolved by the end of Rich Clement's tenure, about 2 years ago.

The technical elements have been thoroughly reviewed again since then.

This year the EPAB has apparently reviewed the DP yet another time, thereby reopening fundamental issues a third time.

Mallinckrodt has paid oversight costs for the succession of review and for preparation of answers.

Mallinckrodt wants unchanging personnel assigned to its DP from now on.

4.4 Request for Final Status Survey Designs

- On the basis of the, then new SRP, we were asked to submit final status survey designs.
  - We do not ordinarily have that information at DP preparation time.
  - Historically we have not been asked to submit detailed survey designs.
  - Historically, we have not been asked to submit procedures to headquarters for approval by license amendment.
- If we had made a best effort, we would have to revise them as a consequence of revised DCGL requested in the NRC letter of November 15.
- The request was narrowed to a few example final status survey designs of kinds of circumstances.
- In lieu of survey designs, we put forth substantial effort to develop and submit a final status survey design guide, practically a procedure.
- In the same time frame, the NRC accepted just a final status survey plan from another licensee:
  - North Site Decommissioning Plan
  - NRC RFI dated September 13, 2000
  - Licensee answers dated October 19, 2000
  - NRC approval by license amendment, June 19, 2001
- We believe more has been asked of us than of the other licensee, and has taken time and effort to reach acceptance. This seems like unequal treatment.

4.5 It seems like the NRC has been unwilling to approve of the CT DP until it developed policies, implementation guidance, and backfitted or ratcheted some review to that SRP. This, the succession of reviewers, and the long time has been discouraging to us about the NRC regulatory process.

4.6 SRP Checklist for Phase 2

- We have been told that practically every item in the SRP checklist except nuclear criticality safety and restricted release are applicable. In effect we are asked to address all items.
- Before then, we should have approved an approved radiation protection plan, quality assurance plan, organization and administration plan, and some other information blocks already accepted in Phase 1 of the decommissioning plan.
- It does not seem worthwhile to have to rebuild them for Phase 2 to satisfy the SRP checklist. Why should we have to rework them again?

4.7 Backfitting/Ratcheting

- The Standard Review Plan appeared after 2 rounds of NRC review and Mallinckrodt response.
- Request for final status survey designs apparently stem from the SRP.
- Last year, Jean-Claude was comparing our derivation of DCGL on the basis of draft ANL information that he could not give me.
- On November 15, 2001 we were asked to derive DCGL anew on the basis of ANL recommendations not available when HM was previously deriving the DCGL.
- The EPAB has apparently reviewed technical issues again, thereby reopening fundamental issues a third time.

4.8 Disposal (Clearance issue)

The NRC seems unwilling to implement its decommissioning rule completely because it *might* adopt a similar *clearance* rule that *might* have incompatibly more restrictive release criteria than the decommissioning rule. Sounds like *stonewalling* or *backfitting on conjecture*.

Even though buildings or land pass final status survey in accordance with its decommissioning plan and the NRC agrees, Mallinckrodt would still have to survey again to satisfy surface activity *Guidelines* in its license condition 16 before it could remove part of a building or any soil from the site without restriction before the license is terminated. Else, it must ship it to regulated burial.

Given:

- the long time and disappointing progress in Phase 1,
- the historical failures of "*de minimis*" and "below regulatory concern," (ref. Appendix A), and
- practical absence of acceptance of anything but surface activity *Guidelines* in FC 83-23 for unrestricted release of material and equipment,

Mallinckrodt would like for the NRC to be willing to give good faith consideration of a request for license amendment application, based on 10 CFR Part 20.2002, to permit of soil and building debris containing up to 5 pCi U^{238}+Th^{232}/g solids with daughters in equilibrium to be disposed in an municipal or industrial waste landfill. Its potential radiological dose can be demonstrated to be only a few mrem/yr.

4.9 Perspective

At this stage of implementation of the decommissioning rule, the approach seems to be that everything is vitally important. This burdens attention and resources and even distracts attention from the most important aspects

The regulatory process for decommissioning could employ its resources more effectively by being more attentive and discriminating about the:

- range of safety and health risk significance in a broad sense; and
- range of importance to safety and health risk of elements within a decommissioning plan.

To enable this, the NRC staff could identify properties that help discriminate relative importance of elements of the Standard Review Plan checklist. Then grade or rate the elements in the checklist according to relative importance. Such a scale could assist decommissioning plan developers and reviewers to use their effort more effectively.

More differentiation between vital specifications versus descriptive information within a decommissioning plan than in the SRP could help provide perspective during preparation, review, and implementation. A chapter stating specifications that are the most important and can only be changed by written authorization by the NRC could be useful. It might borrow useful concepts from Part 50 and Part 70 licensing.

Provisions for what may and may not be revised by internally authorized review and approval could help avoid uncertainty and help improve effective use of resources.

Appendix A

SOME HISTORY OF EFFORT TO DE-REGULATE RADIOACTIVE MATERIAL

The prospect of a material *clearance* regulation seems to be making the NRC reluctant to implement the decommissioning rule to permit removal of building debris from the site without restriction on its disposition before license termination. The following brief history of NRC efforts to de-regulate radioactive material are sufficient cause to discourage any licensee from depending on the prospect of a *clearance* regulation that will be useful.

The Atomic Energy Act of 1954, as amended, authorizes, first the AEC, now the NRC:

> To exempt certain classes or quantities of material or kinds of uses or users from the requirements for a license * * * when it makes a finding that the exemption * * * will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.[1]

10 CFR Part 40.13, Unimportant Quantities of Source Material, exemplifies the application of this authority.

During the late 1970's, the nuclear power industry, coordinated by the UNWMG and the AIF, made an effort to get the NRC to exempt *de minimis* concentration of certain radioactive material it can regulate. The acronym for the effort was called *de minimis*. HM was a technical consultant to UWMG and AIF. HM was co-author of "*de minimus* Concentrations of Radionuclides in Radioactive Wastes" in support of regulatory effort.

In the Low-Level Radioactive Waste Policy Amendments Act of 1985, Congress directed the NRC to establish standards and procedures and act on petitions

> to exempt specific radioactive waste streams from regulation by the Commission due to the presence of radionuclides in such waste streams in sufficiently low concentrations or quantities as to be below regulatory concern.[2]

During the late 1980's and early 1990's, the UNWMG spent about $1 million to $2 million dollars in support. That effort was commonly called *below regulatory concern*.

Negative reaction to the effort caused Congress to effectively abandon its direction by enacting a provision of law that stated:

> No provision of this chapter, or of the Low Level Radioactive Waste Policy Act (42 U.S.C. 2021b *et seq*.), may be construed to prohibit or otherwise restrict the authority of any State to regulate, on the basis of radiological hazard, the disposal or off-site incineration of low-level radioactive waste, if the Nuclear Regulatory Commission, after October 24, 1992, exempts such waste from regulation.[3]

---

[1] Atomic Energy Act of 1954, sec. 81, 42 U.S.C. 2111.

[2] Low-Level Radioactive Waste Policy Amendments Act of 1985. 42 U.S.C. 2021j. enacted Jan 15, 1986.

[3] State Authority to Regulate Radiation Below Level of Regulatory Concern of Nuclear Regulatory Commission. 42 U.S.C. 2023 (a). 1992.

In effect, if the NRC exempts radioactive material from its control over disposal or incineration because it is below regulatory concern for radiological hazard, a state may assume regulation where the NRC quits.

The NRC staff again began an effort to deal with the issue of releasing materials and equipment having some radioactive residue from regulatory control.[4] NRC Commissioners approved the staff to proceed with making a regulation based on radiological dose for *clearance* of materials and equipment having residual radioactivity.[5] This time the effort is termed *clearance*. The NRC has asked the National Academy of Sciences to examine the issue and is awaiting the NAS report, expected in February, 2002.

Its history has been two failures dating back into the 1970's. Even if a rulemaking were successful, the maximum tolerable radiological dose and thus the maximum radioactivity concentration exempted by a *clearance* regulation should be expected to be so low as to be of little practical use to a source or 11.e.(2) byproduct materials licensee to release bulk material from their site without restriction on its disposition. Consequently, the prospect of a *clearance* regulation poses more of a diversion than a help in the foreseeable future.

---

[4] NRC. "Regulatory Options for Setting Standards on Clearance of Materials and Equipment Having Residual Radioactivity." SECY-98-028. Feb. 19, 1998.

[5] NRC Sec'y, J. Hoyle. "Regulatory Options for Setting Standards on Clearance of Materials and Equipment Having Residual Radioactivity." Staff requirements memorandum on SECY-98-028. June 30, 1998.